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SURGICAL INSTRUMENT SERVICE COMPANY, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC.

Plaintiff/Counter-Defendant,

v.

INTUITIVE SURGICAL, INC.,

Defendant/Counterclaimant.

Case No. 3:21-cv-03496-VC

Honorable Vince Chhabria

PLAINTIFF SURGICAL INSTRUMENT SERVICE COMPANY, INC.'S OPPOSITION TO INTUITIVE'S MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT

Hearing: June 8, 2023
Time: 10 AM PT
Courtroom: Courtroom 5, 17th Floor
Judge: The Honorable Vince Chhabria
Complaint Filed: May 10, 2021

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I. INTRODUCTION

Intuitive's Motion asks this Court to take the extraordinary step of jettisoning SIS's otherwise meritorious claims based almost exclusively on the non-public, non-binding, and recanted statements of low-level FDA reviewers who are multiple levels below officials who have been delegated authority to make such decisions. What makes this request even more extraordinary – as SIS explained in its Motion and Intuitive largely ignores – is that plain statutory language and FDA's public, binding pronouncements demonstrate SIS's EndoWrist repair business was not only not willful or in violation of regulations, it was and is proper.

II. FACTS

Intuitive's "Statement of Undisputed Facts" is nothing of the sort. Intuitive mischaracterizes and in quite a few instances misrepresents much of the underlying evidence. And the narrative it spins is contradicted by Intuitive documents and testimony from its own executives, engineering and regulatory leadership, and experts. In the following Sections II(A)-(G), each subsection corresponds to the similarly numbered section in Intuitive's Brief.

A. Innovation in EndoWrists Over the Last 25+ Years Has Been Minimal

1. Intuitive's Monopoly In Surgical Robots for Minimally Invasive Surgery

Although "[redacted]" it is common knowledge "[redacted]." JVH Dec. Ex.1 at p.2. A significant number of surgeons "[redacted]" and [redacted]." *Id.* at Ex.1, p.19; *see also* Ex.2 (An Intuitive marketing manager acknowledging that hospitals "[redacted]"); Ex.3 at -29347 (Intuitive noting that "[redacted]"). According to Intuitive's Chief Product Officer, as of 2019 there were not "[redacted]." *Id.* at Ex.4, 12:13-15, 69:19-24. Thus, "[redacted]." *Id.* at Ex.5. The offering of one of its primary hypothetical

future competitors (Medtronic) was still undergoing clinical trials as of last month, while Johnson & Johnson's system is still years away. *Id.* at Exs.6,7,8. If these products eventually come to market, "[redacted]" include "[redacted]" *Id.* at Ex.4, 59:14-21.

2. EndoWrists Have Been Largely Functionally "Identical" for 20+ Years

Intuitive states that "[l]ike many innovative products, da Vinci systems have evolved over time, and Intuitive has introduced new models from time to time[.]" Dkt. 137 at p.3. Although Intuitive's surgical robots may be innovative, Intuitive ignores SIS's showing (Dkt. 127 at pp.2-3) that innovation in EndoWrists has been minimal since the initial design in the 1990s. Nor does Intuivitive dispute that despite the Xi being "introduced in 2014" (Dkt. 137 at p.3), "[a]lmost all patents on EndoWrists have long since expired" (Dkt. 127 at p.2 n.1).

In a document "[redacted]" Intuitive explained (1) "[redacted]"; (2) "[redacted]"; (3) "[redacted]"; (4) "[redacted]"; and (5) "[redacted]" JVH Dec. Exs.9, 10 at Intuitive-00027299-300. Xi and Si test results are interchangeable due to "[redacted]" *Id.* at -27303. Intuitive's Director of Core Instruments Design Engineering acknowledges that these statements are correct. *Id.* at Ex.12, 11:15-12:4, 48:23-52:10.

Intuitive notes that Si systems have been "phased out[.]" Dkt. 137 at p.3. As Intuitive's Director of Product Marketing, Secondary Markets explained in May of 2018, prior to the start of the "phase out" of Si in 2019 (JVH Dec. Ex.13): "[redacted]" *Id.* at Ex.14. Similarly, a 2016 study on "[redacted]" acknowledged that [redacted]." *Id.* at Ex.15, p.12. Thus, "[redacted]" *Id.* Absent [redacted]" to "[redacted]" there would "[redacted]" to "[redacted]" *Id.* at p.2. So, in 2018 Intuitive decided to "[redacted]r" including [redacted]. *Id.* at Ex 16, -331266.

B. The Use Counter is an Intuitive-Exclusive Means to Extract Exorbitant Pricing

A telltale characteristic of a monopolist is that they can engage in conduct that would not be possible in a competitive market. Intuitive's self-destruct use counter is a one of a kind feature with little, if any, relation to patient safety, that hospitals have no choic but to accept.

1. "Wear and Tear" and "Cleaning and Sterilization" are Not Unique to EndoWrists – But a Self-Destruct Use Counter Is

Intutive declares, without citation to any supporting evidence, that "[i]t was clear from the beginning that use limits would be needed for EndoWrists, with a reasonable margin of safety." Dkt. 137 at p.4. According to Intuitive, EndoWrists are subject to "wear and tear" and "cleaning and sterilization processes[.]" *Id.* at pp.3-4. So are the hundreds of other types of multi-use medical instruments and devices used in surgery, including many that are more complex than EndoWrists such as cabled flexible endoscopes that SIS has been repairing for years. JVH Dec. Ex.17 at 11:20-12:1, 72:21-75:16; Ex.18, ¶¶ 130-135; Ex.19, 115:8-116:8.

But, as both parties' surgeon experts agree, Intuitive's EndoWrists are the only instruments with a self-destruct use counter. *Id.* at 20, 40:11-42:11; Ex.11, ¶ 64.

Intuitive poses the straw-man argument that "SIS has no evidence to dispute that EndoWrists are subject to failure from wear-and-tear; nor does it have evidence that they can reliably be used indefinitely."[1] Dkt. 137. SIS has never made such a contention. Rather, SIS contends that EndoWrists can be inspected and repaired to original specifications to allow additional uses. JVH Dec. Ex.17 at 72:21-75:16. This is similar to what SIS – *i.e.*, *Surgical Instrument Service Company* – has done for millions of used surgical instruments in over 50 years in business. *Id.* at 10:23-12:1; Ex.23, 33:14-34, 36:18-37:20. This is a normal and financially critical part of hospital operations. *Id.* at Ex.24, ¶¶ 24-26, 32-33. The process SIS was planning to use for its own repairs (before Intuitive's threats to hospitals) is a robust process that ensures repaired EndoWrists are returned to their original specifications and fully accounts for wear and tear.[2] *Id.* at Ex.21, ¶¶ 9, 64-88; Ex.17 at 28:13-29:24; Ex.25 at 33:9-19. FDA approved an almost identical process for Iconocare's labeling and commercial distribution of Iconocare-branded used EndoWrists. *Id.* at Ex.21, ¶¶ 259-272.

2. The Intuitive-Exclusive Use Counter Merely Counts Attachments to the Robot and does Not Capture nor Consider any Relevant, Surgery-Related Information

Again without citation to evidence, Intuitive declares that "[e]ach EndoWrist has a computer chip that *tracks* critical information about the instrument, including the number of times it has been used." Dkt. 137 at p.5 (emphasis added). But it is undisputed that the only

[1] Although EndoWrist repairs cannot be repeated "indefinitely," Intuitive's own massive data sets show a virtually identical failure rate for each use as uses increase. Because the failure rate does not increase with more uses, an EndoWrist may be repaired multiple times if it passes the rigorous inspection and testing employed in third-party repair. *E.g.*, JVH Dec. Ex.21 at ¶¶ 280-282. Intuitive's claims to the contrary are based on a flawed analysis of a small and "noisy" data set (*id.* at ¶¶ 273-276, 279) and outright manipulation of the data sample sizes and sample selection (*id.* at ¶ 277-278). *See also id.* at Ex.22, 100:21-103:22.

[2] Intuitive criticizes third-party repair procedures that don't "perform a full refurbishment" "by replacing the cables or pulleys." Dkt. 137 at p.6. There is no evidence that replacing cables or pulleys is necessary. Instead, the undisputed evidence shows that inspection and cable tensioning performed in third-party repair returns EndoWrists to original specifications. *E.g.*, JVH Dec. Ex.21 at ¶¶ 38, 43-44, 49-50, 81, 97, 105, 129, 135, 156, 171, 190-201 (discussing "visual inspection" of components and "cable tensioning procedure").

thing that EndoWrist chips "track" – for Si or Xi – is how many times an EndoWrist attaches to a robot and makes an initial movement, known as "following" mode. JVH Dec. Ex.26 at 12:7-23. Other than the decrementing the counter, the chip is one-time programmable and the values in the chip are not changed. *Id.* at Ex.27, 58:3-17, 110:24-111:8. It is also undisputed that the counter does not track useful information about surgeries like time or severity of usage.[3] *Id.* at Ex.28, 24:7-26:7, 32:19-33:17. EndoWrists must be thrown away "[redacted] *Id.* at 33:13-17; *id.* at Ex.21, ¶¶ 215-225. Nor does the counter monitor or track misuse, damage, or any physical characteristics of the instruments. *Id.* at Ex.21, ¶¶ 226-242. Thus, hospitals must perform an inspection "for damage or irregularities" before every use. *Id.* at Ex.30, p.518.

Intuitive also states that "[f]or X/Xi systems, Intuitive *upgraded* to a wireless connection; this required the chip to be encrypted for security purposes to avoid tampering." Dkt. 137 at p.5 (emphasis added). Calling the switch from a wired connection an "upgrade" is peculiar – both wired and wireless chips are commodity components with numerous configurations of memory size, transmission speeds, and the like. JVH Dec. Ex.31 at 146:10-149:10; *id.* at Ex.32, ¶¶ 15-17. Because an EndoWrist cannot function when not rigidly mechanically attached to a robot arm, the fact that wireless "[redacted]" is useless. *Id.* at Ex.31, 150:19-153:8; *id.* at Ex.32, ¶¶ 13-14. In fact, Intuitive lead engineers discussed the actual reasons for the "upgrade" during Xi product development: [redacted]." *Id.* at Ex.33; *see also id.* at Ex.34 ("[redacted]" is "[redacted]

[3] The Intuitive *system*, on the other hand, tracks detailed information about every use of a particular EndoWrist instrument, including time of usage and detailed motor torque data, which in turn equates to severity of use. JVH Dec. Ex.26 at 13:17-17:14. This information is stored for both Si and Xi systems. *Id.* at 17:15-18:23. Intuitive's Vice President of Design Engineering agrees that time of use and particularly severity more accurately captures wear and tear. *Id.* at Ex.28, 32:19-33:17. Yet, while it provides much of this information in its "My Intuitive" App, it retains its simplistic per-attachment counter for self-destruct purposes. *Compare id.* Ex.26, 18:25-19:10, *with* https://www.youtube.com/watch?v=Pxo13Okk4JA ("Your data, your truth | My Intuitive"), *and* Ex.29, 145:16-146:1, 150:22-152:17.

[redacted]"); *id.* at Ex.27, 23:15-17, 110:15-111:8 (Intuitive engineering director admitting that noboty has tried to access other Xi data and doing so "[redacted].").

3. The Use Limit Values were Set for Financial (Not Engineering) Reasons and Intuitive Then Tested to Its Marketing-Set Use Limit Values

Intuitive contends that "the use limits were *preceded* by years of exhaustive safety testing[.]" Dkt. 137 at p.5 (emphasis added). It has the sequence of events backwards. As explained by Intuitive's VP of Design Engineering, "[redacted]" and [redacted]" JVH Dec. Ex.28 at 64:5-19; *see also id.* at 65:19-25 (agreeing that "[redacted]"). In other words, rather than "[redacted]" Intuitive starts with its marketing-determined use limits and confirms that these limits are satisfied with a statistical degree of certainty. *Id.* at Ex.35 at -01085683-84. Thus, Intuitive "[redacted]." *Id.* As an example of how this undercounts the life of an EndoWrist, during Xi "life testing" most instrument types never experienced a single failure. *Id.* at Ex.36, pp.51, 55, 56, and 60. Were Intuitive to test to failure, significantly higher numbers of lives "[redacted]." *Id.* at Ex.35.

Intuitive says it "has sought and obtained FDA clearance for 'extended' use limits for certain X/Xi EndoWrists that range as high as 18 uses." Dkt. 137 at n.3. But Intuitive did not "seek" FDA clearance for this program; instead, it believed that increasing use limits for EndoWrists did not require a 510(k). JVH Dec. Ex.37 at 38:19-39:10. Its Director of Regulatory Affairs Strategy believed it was proper to sell extended use EndoWrists without a 510(k), and to continue selling such instruments while a 510(k) was pending. *Id.* at 35:3-36:11, 38:19-41:7; *see also* Ex.38. Similarly, when Intuitive considered a refurbishing program, its "[redacted]" was that FDA [redacted]" *Id.* at Ex.39, -423574.

Intuitive claims that "[t]hese extended use limits were made possible by years of incremental product improvements in the more advanced X/Xi instruments that were not

applicable to the older S/Si instruments, which remain prone to earlier failure." Dkt. 137 at n.3. To the contrary, the extended use program is yet another example of Intuitive ignoring science in pursuit of monopoly profits. At the time when Intuitive decided to pursue the extended life program for Xi EndoWrists, Si EndoWrists were in fact about [redacted]% as "prone to earlier failure" compared to Xi. *See* JVH Decl Ex.41 at -967511 (showing a [redacted]% failure rate for Si EndoWrists versus [redacted]% failure rate, and similar or greater differnces over time); *see also* JVH Decl Ex.40 (dicussing, in January 2019, "RMA analysis for possible life extension"), and Ex.41 (presenting, in February 2019, RMA data with lower Si failure rate)

Even Intuitive's extended use testing did not test to failure. *Id.* at Ex.35 (noting for "[redacted]" that significantly higher "[redacted]" if they "[redacted]"). And despite minimal changes to 5+ year-old insrument designs, Intuitive imposed incremental price increases that were typically multiple times the total cost of manufacture. *Compare id.* at Ex.42, -671218 (increasing prices by [redacted] dollars) *with id.* at Ex.43 (listing costs of goods sold in the [redacted] of dollars).

4. FDA Never Substantively Reviewed Intuitive's Use Limits, Required Intuitive to Have a Use Counter, or Required the Counter to Self-Destruct

Intuitive argues "[t]hat FDA clearance, and the resulting labeling of the devices, reflect use restrictions developed through extensive testing and reviewed by FDA for reasonable assurance of safety and effectiveness. Rosa Dec. ¶ 23; Cahoy Dec. Ex. 10 ¶ 75-76." Dkt. 137 at p.3. The underlying "evidence" cited by Intuitive – Rosa Dec. ¶ 23 and Cahoy Dec. Ex. 10 ¶ 75-76 – consists of unsupported statements of the Intuitive declarant for the present motion and its FDA "expert." In fact, the relevant paragraph from Intuitive's expert attempts to explain away the relatively fleeting discussion of use limits in Intuitive's FDA filings – *i.e.*, why "[t]he fact that the 'indications for use' in the 510(k) summaries do not specifically state that EndoWrist instruments are subjected to limited use makes no difference[.]" Cahoy Dec. Ex. 10 ¶ 76. In sum, although Intuitive occasionally alludes to its use counter in FDA filings, FDA has not required EndoWrists to have a use counter or substantively examined Intuitive's

use limits, let alone required that the use counter operate as a self-destruct mechanism. As was explained by Intuitive's Senior Director of Regulatory Affairs, "[redacted]" JVH Dec. Ex.44.

C. Intuitive's Egregious Contracts With Hospitals And Heavy Handed Enforcement

Intuitive argues that its "agreements confirm that the da Vinci system should be used only with approved EndoWrists and provide that use of a non-approved instrument may give Intuitive the right to discontinue service" (Dkt. 137 at p.5), but neglects to mention that what it discontinues is serivce for *the robots*, turning them into expensive paperweights and shutting down entire robotic surgery programs. JVH Dec. Ex.4 at 261:23-263:3. As Intuitive executive stated, "[redacted]." *Id.* at Ex.45, 136:2-5. In addressing an Intuitive threat letter to an SIS customer with 40 or more million-plus dollar robots, Intuitive's 30(b)(6) witness regarding its threat-letter campaign to hospitals couldn't tell whether Intuitive was threatening to terminate the entire robotic surgery program, or just the contract for a particular robot. *Id.* at Ex.46, 12:17-22, 88:17-89:1, 92:21-94:17. As one Senior VP remarked, following Intuitive's decision to quickly drop its potential refurbishment program, "[redacted]out" rather than "[redacted]" *Id.* at Ex.47, -604054. It was these threats to hospitals (including false statements about FDA requirements[4]), that caused hospitals to stop using repaired EndoWrists, including those serviced by SIS. *E.g.*, *id.* at Ex.46, 76:11-76:22 (Intuitive confirming that repair activity escalated in late 2019 but quickly lessened based on Intuitive "interacting" with hospitals); *id.* at Ex.17, 42:14-44:19 (SIS explaining that after Intuitive threats "all of our customers and the people we talked to were very afraid of having their robotic program shut down").

[4] A 2020 Deutsche Bank study noted "[redacted]" and "[redacted]." JVH Dec. Ex.48 at -566057 (original emphasis). That study noted that [redacted] *Id.* at -566055.

D. Rebotix and Iconocare Explictly Sought Approval From FDA to Repackage, Relabel, and Resell EndoWrists for Commercial Distribution; This is Different from Repair of Hospital-Owned Instruments, which FDA has Not Interfered With

As discussed at length in SIS's Opening brief, FDA does not engage in enforcement against ISOs for repair of hospital-owned instruments as so-called "remanufacturing," and indeed, after over 20 years of struggling, still hasn't adopted standards for potentially doing so in the future. Intuitive cannot transform a few non-binding pronouncements of low-level FDA employees that are contrary to this 20+ year history and FDA's explicit public pronouncements[5] into a *de facto* change of FDA policy. JVH Dec. Ex.49 at ¶ 28; *see also id.* at Ex.50 (https://www.fda.gov/media/80114/download, listing FDA officials with delegated authority on "Classification of Devices," but not including "Team Lead" or "Biomedical Engineer"). SIS is not engaging in "disparagement" (Dkt. 137 at p.15) by pointing out the undeniable facts that the only FDA employees to ever support Intuitive's position are far down in FDA's rather massive bureaucratic pyramid,[6] have no authority to make policy,[7] and have made their non-public, unenforceable, and recanted statements[8] at the behest of their primary regulatory customer, Intuitive. *E.g.*, Dkt. 127-26 (Intuitive requesting FDA action against Rebotix on January 29, 2020); Dkt. 127-48 (on February 28, 2020, an FDA employee writing Rebotix that "we believe that 510(k) is needed before you continue your operation").

What Intuitive refers to as a "loophole" happens to be the exact statutory language that the OEMs have been unsuccessfully trying to change for years (*see* Dkt. 127 at pp.11-13):

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[5] For example, Intuitive ignores the fact that FDA explicitly posed a scenario – but declined to issue even *draft* guidance – where "[s]ome components/parts/materials have a defined intended use life which limits the life expectancy of the device ... [and] [a]ctivities are performed to extend the device's intended use life." Dkt. 127 at pp.17-18.

[6] *E.g.*, JVH Dec. Ex.51 at ¶ 11; *id.* at Ex.49, ¶ 28. The FDA officials with delegated authority on "Classification of Devices" do not include "Team Lead" or "Biomedical Engineer." Ex.50. The full list of FDA officials delegated decision-making authority on various issues is here: https://www.fda.gov/about-fda/staff-manual-guides/delegations-authority-volume-ii-1400.

[7] "These officials [listed in Ex.50] may not further redelegate these authorities" at all, let alone to a "Team Lead" or "Biomedical Engineer." *Id.* at Ex.50, p. 4.

[8] Intuitive disingenuously states that "FDA identified for Rebotix ways in which it could have the determination reduced to a form it could appeal" but "[t]here is no record of Rebotix accepting that invitation." Dkt. 137 at p.15. But the only proposal from the FDA reviewer to "have the determination reduced to a form [Rebotix] could appeal" was to "submit an application such as a 510(k)" – *i.e.*, to concede the exact issue in dispute. Dkt. 127-49.

"The term 'manufacture, preparation, propagation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user." 21 U.S.C. § 360(a). When Rebotix originally sought 510(k) approval in 2014, and Iconocare in 2021, they explicitly sought to "chang[e] the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the ... device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user." Cahoy Dec. Ex. 21 at -170422, 24 (Rebotix, in its 2014 submission, submitting pages "[redacted]" of "[redacted]" and noting its "[redacted]"); Cahoy Dec. Ex. 42 at -86097, 99, and 104 (Iconocare addressing labels for for commercial distribution); Cahoy Dec. Ex. 40 at -357814, 818 (FDA stating that Iconocare "may, therefore, market the device," and including a 510(k) summary stating that "[e]ach individual device is tested for appropriate function of its components **prior to packaging and labeling operations**"). Simply put, the voluntary submission of a 510(k) by a third party, particularly under completely different circumstances of a relabeling and commercial distribution business model, has no bearing on whether SIS needed to submit a 510(k). JVH Dec. Ex.51 at ¶¶ 117-122.

There is no dispute that SIS does not "chang[e] the container, wrapper, or labeling of any drug package or device package" or engage in commercial distribution of EndoWrists. JVH Dec. Ex.51 at ¶¶ 100-101, 119, 121. And FDA has never made an official pronouncement that captures SIS's activities as an ISO. Whatever an FDA "Team Lead" may say in "informal communications" that FDA declines to enforce, Intuitive cannot rewrite the law or create official FDA policy in a manner that reads the entire 3rd party repair industry out of existence, particularly where FDA itself has repeatedly declined to do so. Dkt. 127 at pp.11-18; JVH Dec. Ex.51 at ¶ 11, 100-114; *id.* at Ex.49, ¶ 28; *id.* at Ex.50.

E. Intuitive Never Distinguished Between FDA-Approved Processes and Other 3rd Party Repairs Until It Recently Adopted a New Litigation Strategy

As discussed in § II(C) above, Intuitive's "Response" to third-party repair has been to threaten hospitals' robotic surgery programs. Although it now says that "Intuitive has made clear that use of an FDA-cleared remanufactured EndoWrist does not breach any customer's contract or otherwise subject a customer to adverse action by Intuitive" (Dkt. 137 at p. 9), this "clarification" is barely two months old. Compare Dkt. 137-2 at ¶ 45 (discussing clarification "[a]s of March 1, 2023) *with* JVH Dec. Ex.52 (most recent prior capture from Internet Archive, showing no such policy). Having already wielded its monopoly power to shut down EndoWrist repair, Intuitive is attempting to run out the clock by *de facto* requiring unnecessary FDA clearances, contrary to statute, regulations, and 20+ years of FDA guidance.

Intuitive's threat letters – which have separate sections on "Impact to Regulatory Clearances" and "Your Contract with Intuitive" – make no such distinction. *Id*. at Ex.53, -986535-56. The "Your Contract" section never mentions FDA clearance, and instead threatens to shut down robot support based on *any* repair of EndoWrists or similar activities. *Id.* at -56 ("repair, refurbishment, or reconditioning not approved by Intuitive" is "prohibited"); *id.* ("Intuitive may terminate the Agreement immediately upon written notice" if the hospital or a third party chooses to "modify, disassemble, reverse engineer, [or] alter ... Instruments[.]"); *id.* at -57 ("Should Intuitive or its personnel determine … that the System has been used with instruments refurbished or modified by an unauthorized third party, Intuitive may not provide service for such a System.").

Intuitive's sales agreements do not provide an "FDA exception" or even mention FDA. *Id.* at Ex.54. And none of Intuitive's executives mentioned an FDA exception under deposition. *E.g.*, *id.* at Ex.46, 83:24-84:12 ("[redacted]."); *id.* at Ex.55, 197:11-198:23 (agreeing that the "[redacted]" including that even if "[redacted]ales

[redacted]graspers"). Intuitive's recent epiphany, only after it kneecapped the EndoWrist repair business, should be ignored as the litigation-concocted posturing it is.

F. EndoWrist Repair Became a Substantial Competitive Issue Once SIS Entered the Market based on SIS's Relationships, Reputation, and Expertise

As SIS explained in its opening brief, it has 50+ years of experience in instrument repair, including with numerous types of surgical instruments more complex than EndoWrists. Dkt. 127 at pp.4-6. Once it brought its expertise and relationships to EndoWrist repair, demand escalated in late 2019, with "monumental" demand from hospitals[9] and a signed agreement with the country's largest GPO. *Id.* That all quickly came to a stop when Intuitive threatened to shut down hospitals' robotic surgery programs. *Id.* at pp.6-7. Intuitive does not dispute these facts, but instead attempts to cast aspersions at SIS based on mischaracterizations of the facts. Virtually all of those mischaracterizations come down to one core issue – As a monopolist engaged in egregiously anticompetitive acts, Intuitive shut down the EndoWrist repair business in the United States by early 2020. Thus, while SIS's activities were stopped in 2020, it was moving the repairs to its own facilities and was finalizing its contracts with suppliers to service the monumental demand for repaired EndoWrists. JVH Dec. Ex.17 at 26:10-27:20, 28:13-29:24, 30:5-15, 39:13-14, 41:23-42:10, 84:1-9, 86:10-87:4. All of those suppliers would have continued to work with SIS,[10] had Intuitive not shut down the EndoWrist repair business. *Id.* at 39:13-24; *Id.* at Ex.19, 108:15-109:8; Ex.57 at pp.7-11.

[9] Intuitive falsely states that the monumental demand was for the "recovery" program. Dkt. 137 at n.8. To the contrary, although there were instances where SIS would discuss the recovery program with hospitals (Cahoy Dec. Ex.84 at 58:6-61:20), hospitals' monumental interest was in "repair." *E.g.*, JVH Dec. Ex.25 at 43:19-45:22 (describing "monumental" interest that "covers well over 2,000 hospitals in the United States" for the "repair program for Xi instruments"); *see also* Ex.56, at 50:19-51:24 (explaining that one reason for the "monumental level of interest in EndoWrist repair" was that hospitals "hemorrhage money to Intuitive Surgical." *Id.* at; *see also id.* at 52:5-53:8 (discussing GPO interest in repair).

[10] Intuitive criticizes SIS for using materials from Rebotix and not performing independent testing of the Rebotix process. Dkt. 137 at p.10. SIS has decades of experience with the principals of Rebotix and evaluated the repair process in person at SIS and Rebotix. JVH Dec. Ex.17 at 82:20-83:24, 90:7-91:15; *id.* at Ex.25, 22:12-24, 23:9-24:16.

G. X/Xi EndoWrists are Substantially Identical to S/Si From a Functional Persepective, and Would Have Been Capable of Reset Long Ago Absent Intuitive's Conduct

As discussed in detail *supra* at § II(B)(2), Intuitive's recently contrived attorney arguments that a wireless RFID chip for Xi was an "improvement" over its prior, reliable, pogo-pin wired connection are belied by common sense and Intuitive's contemporaneous statements and documents from Xi product development. RFID chips and EEPROMs are commodity components with a variety of specifications, and it makes no sense to add a wireless component to an EndoWrist that rigidly physically connects to a robot arm in order to function.[11] *E.g.*, JVH Dec. Ex.32 at ¶¶ 10, 12-16; *id.* at Ex.58, ¶¶ 37-59. Indeed, for its [redacted] it is using the purportedly inferior wired pogo-pin connection for its [redacted]. *Id.* at Ex.27, 132:8-138:2.

Intuitive argues that nobody has bypassed Xi encryption, selectively citing to deposition testimony. Dkt. 137 at p. 11. To the contrary, in an excerpt omitted from Intuitive's brief, "[redacted]." *Id.* at Ex.59, 42:1-11, 38:9-42:11. [redacted]. *Id.* at Ex.19, 60:9-25, 89:10-25; *see also id.* at Ex.60, 141:14-142:12 [redacted]"). Third parties would have been able to bypass Xi encryption much earlier had Intuitive not dried up funding through anticompetitive acts. *Id.* Ex.19, 75:17-76:1, 96:13-97:8; *id.* at Ex.59, 15:13-22, 42:11-44:12; *id.* at 58, ¶¶ 28-36. As a lead Intuitive engineer explained, [redacted]" *Id.* at Ex.27, 123:2-17. As Intuitive acknowledged, [redacted]"[12] *Id.* at 123:18-21.

[11] Intuitive's discussion of FDA guidance regarding wireless communications is beside the point. Intuitive only needed to address wireless security because of its nonsensical decision to use a wireless connection for rigidly physically connected EndoWrists.

[12] Although Intuitive's encryption expert was unable to discuss and refused to consider the encryption of Xi EndoWrists because he had never thought about it (JVH Dec. Ex.31 at 177:3-178:13, 182:4-186:10, 187:5-189:7, 190:2-6, 196:16-198:19), he similarly acknowledged that decrypting any system is a matter of "legwork." *Id.* at 205:1-206:20.

III. ARGUMENT

"In antitrust cases, … general [summary judgment] standards are applied even more stringently and summary judgments granted more sparingly." *Beltz Travel Serv. v. Int'l Air Trans. Ass'n,* 620 F.2d 1360, 1364 (9th Cir. 1980). Intuitive seeks summary judgment on all of Plaintiff's claims, despite clear factual disputes on each underlying issue. As to SIS's motion, Intuitive's only argument is that the Court should override nearly 50 years of statutory and regulatory history in favor of scattered statements of low-level FDA employees who have no authority to set FDA policy, and to whom authority may not even be delegated.

A. Intuitive's Conduct Caused The Antitrust Injury In This Case -- Not FDA

Intuitive argues SIS has not incurred an antitrust injury because of FDA's regulatory scheme. As an initial matter, the proximate causation of antitrust injury in this case flows from Intuitive's conduct in the EndoWrist repair and replacement aftermarket. As detailed at §§ II(B)-(C) *supra* and Dkt. 127 pp. 2-8, Intuitive has taken anticompetitive steps to prevent third parties from repairing EndoWrists, effectively requiring hospitals to throw away instruments capable of repair and buy new ones from Intuitive. The objective of antitrust policy is to maximize consumer welfare by encouraging firms to behave competitively. *City of Oakland v. Raiders,* 20 F.4th 441, 457 (9th Cir. 2021). The harm incurred by SIS was due to Intuitive leveraging its surgical robot monopoly to achieve and maintain a monopoly in EndoWrist repair and replacement. This is precisely the kind of harm to competition antitrust laws were intended to prevent. See *Pool Water Prod. v. Olin Corp.*, 258 F.3d 1024, 1034 (9th Cir. 2001).

Intuitive contends that SIS's business "failed for the simple reason that the governing regulatory regime does not permit that activity without a regulatory clearance that SIS and Rebotix did not have." Dkt. 137 at pp.16-17. First, Intuitive is wrong on causation. The undisputed facts are that there was substantial demand for SIS's services despite no FDA approval. *E.g.*, *supra* at § II(F); Dkt. 127 at pp. 4-6. That business was shut down by Intuitive's threats to shut down hospital robot programs. *E.g.*, *supra* at § II(C); Dkt. 127 at pp. 6-7. Second, Intuitive's cited cases (Dkt. 137 at p.17) merely stand for the proposition a plaintiff cannot establish antitrust injury if the economic activity that it claims the defendant prevented

it from pursuing was *unquestionably* unlawful under the governing statutes and/or regulatory schemes.[13] This is simply not the case here. *E.g.*, *supra* at §§ II(B)(4) & II(D); Dkt. 127 at pp. 9-23. Although SIS does not contest the general rule, at best there are questions of fact as to whether SIS engaged in "remanufacturing", and no amount of (recanted) statements from low-level FDA employees with no delegated authority can change that.[14]

B. Intuitive's Restraints Harm Competition Through Substantial Anticompetitive Effects In The EndoWrist Repair And Replacement Aftermarket -- And Have No Procompetitive Or Regulatory Justifications.

Intuitive asserts that "[u]nder each of SIS's theories, Intuitive's conduct can be found to violate the antitrust laws only if it injured competition and was not supported by non-pretextual justifications. *American Express*, 138 S. Ct. at 2284." Dkt. 137 at p.18. Intuitive distorts the controlling law and ignores genuine issues of material fact in this case.

Intuitive pays lip service to the rule of reason requirement that it must justify its challenged restraints by showing they have nonpretextual procompetitive benefits. However, Intuitive never really even attempts to make that showing. Apparently recognizing this fatal weakness, Intuitive takes a different tack, effectively re-writing the rule of reason test by improperly substituting for "procompetitive rationale" a "reasonable basis" standard. Intuitive then compounds its error by focusing on the wrong conduct. While arguing that a "reasonable basis" exists, Intuitive only discusses why designing EndoWrists with a usage counter does not violate the antitrust laws, rather than also showing why a "reasonable basis" existed for making the counter a self-destruct mechanism, or for its later conduct which

[13] In each of the cases cited, there was a clear violation of the law. Due to space limitations, the clear violation is not listed for every case, but the *Modesto* case is illustrative. *Modesto Irrig. Dist v. Pac. Gas & Elec. Co.*, 309 F. Supp.2d 1156 (N.D. Cal. 2004), aff'd 158 F. App'x 807 (9th Cir. 2005) (no antitrust injury because plaintiff failed to obtain approval from a local commission to provide electricity, and therefore, was "not a lawful competitor" of defendant).

[14] Intuitive cites in its Opposition and Cross-Motion for Summary Judgment arguing that the Court should "apply the deference ordinarily accorded FDA in the interpretation of its own regulations and governing statute, *see Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 981-82 (1986)". Dkt. 137 at p.16. The issue before the Supreme Court in *Young* involved a situation where the FDA had taken clear, definitive and final public action on the issue in question, which was announced by publication in the Federal Register. *Id.* at 978. FDA has taken no such action here. *See supra* § II(B)(4) & II(D); Dkt. 127 at pp. 13-18.

effectively shut down competition in the EndoWrist repair and replacement aftermarket. Even with respect to the usage counter, Intuitive misrepresents the facts. FDA never required that Intuitive incorporate a usage counter in the EndoWrist instruments. *E.g.*, *supra* § II(B)(4). Intuitive also attempts to bolster its "reasonable basis" justification by erroneously arguing that it had a duty and authority to police the resetting of EndoWrist usage counters. Even accepting that a "reasonable basis" justification can meet Intuitive's burden under the rule of reason, there is at least a substantial factual dispute about whether less restrictive means were available to Intuitive. *E.g.*, *supra* § II(A)(2) & II(B)(1)-(3).

1. Intuitive Never Even Argues For A Procompetitive Rationale

Intuitive argues that "the undisputed facts establish that Intuitive's conduct was supported by legitimate justifications" (Dkt. 137 at p. 19), tellingly reading the word "procompetitive" out of its argument. Intuitive has offered no evidence that its tying and exclusive dealing restraints, or monopolization of the EndoWrist repair and replacement aftermarket, have any effect to stimulate competition. *See NCAA v. Alston*, 141 S. Ct. 2141, 2151 (2021). The undisputed evidence is that they do not. *E.g.*, *supra* § II(A), II(C), Dkt. 127 at pp. 6-8. Intuitive tacitly concedes that there is no nonpretextual procompetitive justification for its conduct as a whole (Rule of Reason step 2), but as discussed below, instead argues that the Court should focus solely on whether Intuitive had a "reasonable basis" for its self-destruct use counter.

2. Intuitive Improperly Substitutes A "Reasonable Basis" Test And Thereafter Misapplies It By Misrepresenting The Facts

Intuitive substitutes a regulatory justification defense for its burden of establishing a nonpretextual justification for its anticompetitive conduct. It contends that its vertical restraints were required in order for Intuitive to comply with FDA regulations. Intuitive is not entitled to any such "get out of jail free card". In *Phonetele, Inc. v Amer. Tel. & Tel. Co.*, 664 F.2d 716 (9th Cir. 1981), one of the cases Intuitive invokes to support this argument, the Ninth Circuit observed that such a defense was akin to a claim of immunity. But "[a]n implied immunity may be found only where there is 'a convincing showing of clear repugnancy between the antitrust laws and the regulatory system.'" *Id.* at 726 (citations omitted).

Intuitive has not come close to establishing that, at the time of its anticompetitive acts, it had "a reasonable basis to conclude that its actions were necessitated by concrete factual imperatives recognized as legitimate by the regulatory authority", specifically FDA.[15] *Supra* § II(B)(4); Dkt. 127 at pp. 9-18. Indeed, its recent contrived efforts to recast its shut-down of hospitals' robotic surgery programs as about FDA approval, not its heavy-handed enforcement of egregious contractual terms, are belied by its conduct and testimony. *E.g.*, *supra* § II(C) & II(E). As actions of FDA officials with actual authority and its trade association show, Intuitive's shutdown of hospital robot programs and self-destruct counter are not required (or even permitted). *E.g.*, *supra* § II(B)(4), II(D); Dkt. 127 at pp.11-18.

3. FDA Does Not Require, or Even Allow, Intuitive to Police the Market

Intuitive argues it is compelled to police its view of what FDA requires. But it cites no authority for the proposition that FDA deputizes device manufacturers to police third party conduct, let alone through conduct that would otherwise violate the Sherman Act. There is no "safety" exemption from the antitrust laws,[16] and, as described above, whether Intuitive had a reasonable basis to conclude that a use limit self-destruct was necessary is at least a factual dispute. Even if Intuitive could show it believed it needed to impose a self-destruct on EndoWrists in order to obtain FDA clearance to market them, it cannot possibly show that its self-appointed role as "510(k) police"—complete with threats to stop servicing hospitals' robots and void their warranties—was in any way compelled by regulatory authority.[17]

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[15] Intuitive attempts to bolster its position by citing in passing to four additional cases. Dkt. 137, at p.20 n. 14. Each case is distinguishable because they all involve specific regulations that clearly required the specific action. That's not the case here. Dkt. 127 at pp. 13-18.

[16] "In our complex economy the number of items that may cause serious harm is almost endless," but "[t]he judiciary cannot indirectly protect the public against this harm by conferring monopoly privileges on the manufacturers." *Nat'l Soc. of Pro. Eng'rs v. U.S.*, 435 U.S. 679, 695–96 (1978); see also *FTC. v. Ind. Fed'n of Dentists*, 476 U.S. 447, 463–64 (1986) (finding anticompetitive conduct not justified by "noncompetitive 'quality of care' justifications"); *Wilk v. Am. Med. Ass'n*, 895 F.2d 352, 361 (7th Cir. 1990) (similar); *Teladoc, Inc. v. Texas Med. Bd.,* 112 F. Supp. 3d 529, 540 (W.D. Tex. 2015) (similar).

[17] Intuitive cites product liability cases to support its argument. Intuitive's anticompetitive conduct is not equivalent to providing a warning that a manufacturer's own product has dangerous characteristics.

To the contrary, Intuitive's own foundational business plans clearly show that the use limits were created and implemented as a way to "[redacted]" and restrict the "[redacted]" as part of the company's plan to "[redacted]"—in other words, to artificially increase Intuitive's profits, not promote safety or compliance with FDA requirements. JVH Dec. Ex.61 at -595673, -675, -682; *see also id.* at Ex.62 at p.6 ("[W]e can sell the instrument for a fixed number of uses … and effectively price our EndoWrist instruments on a per-procedure … basis"). Although Intuitive now argues that "the determination that use limits were needed" occurred "long before there was any suggestion that third parties" repair services surfaced (Dkt. 137 at p. 20), Intuitive ignores that it developed this business model nearly three decades ago, long before "[redacted]" or even "[redacted]." *Id.* at Ex.61, -691. And Intuitive points to no evidence that FDA later required it to take any specific actions, such as those challenged here, to enforce use limitations.

4. Procompetitive Efficiencies Could Be Achieved Through Less Restrictive Means

Even if Intuitive could carry its burden of showing a procompetitive purpose, there are issues of fact as to whether any alleged procompetitive efficiencies could be reasonably achieved through less restrictive means, such as not including a self-destruct, using time or severity of use, or educating hospitals. *E.g.*, *supra* § II(A)(2), II(B)(1)-(4), II(C), II(G). It is a direct consequence of Intuitive's supracompetitive pricing and bullying of hospitals that demand for repair is so high. It could listen to customers. What Intuitive may not do is impose unlawful restraints on hospitals through coerced contractual prohibitions to eliminate repair.

C. Intuitive's Switch To Enhanced Encryption For Its X/Xi EndoWrists Is Further Anticompetitive Conduct That Harms Competition in the EndoWrist Repair and Replacement Aftermarket

Intuitive argues that its abandonment of the S/Si wired design and subsequent adoption of a wireless design for the X/Xi the usage counter was a totally innocent "product enhancement". Dkt. 137 at pp.22-24. As support for this position, Intuitive primarily relies on *Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp.*LP, 592 F.3d 991 (9th Cir. 2010). The Ninth Circuit in *Allied,* however, cautioned:

> "[C]hanges in product design are not immune from antitrust scrutiny and in certain cases may constitute an unlawful means of maintaining a monopoly under Section 2. * * * [I]ntroduction of a new and improved product design could constitute a violation of Section 2 where "some associated conduct ... supplies the violation." (*Id.* at 998-999 (citations omitted)).

Proof of unlawful actions associated with introduction of an "improved" product design, including an anticompetitive abuse or leverage of monopoly power or a predatory or exclusionary means of attempting to monopolize the relevant market, can establish a violation of Section 2 of the Sherman Act. *Id.* at 1000. The claim that a product design change constitutes an unlawful means of maintaining a monopoly under Section 2 is bolstered when the defendant fails to provide a "procompetitive justification" for its conduct. *Id*. at 998. "Evidence of an innovator's initial intent may be helpful to the extent that it shows that the innovator knew all along that the new design was no better than the old design, and thus introduced the design solely to eliminate competition." *Id*. at 1001. Additionally, "[a] monopolist's discontinuation of its old technology may violate Section 2 if it effectively forces consumers to adopt its new technology."[18] *Id.* at 1002.

As discussed above (*see supra* §§ II(A)(2), II(B)(2) & II(G)), there are numerous questions of fact regarding whether or not there is a procompetitive justification for changing the chip and its security on the X/Xi instruments. It's for a jury to decide if Intuitive's litigation-inspired post-hoc justifications are legitimate, or, if Intuitive's true motivations are consistent with what its own documents said at the time – "[redacted]" JVH Dec. Ex.33. Intuitive has made no showing that its wireless design change improves EndoWrists by providing a new benefit to hospital customers, unless being able to wave an unattached EndoWrist around next to a robot

[18] There is also a genuine issue in dispute regarding whether Intuitive has taken steps to force customers to switch from earlier generation S/Si systems, such as discontinuing sales of S/Si EndoWrists and surgical robots, phasing out technical support for S/Si da Vinci systems, and aggressively pricing to encourage the switch to Xi. *Supra* § II(A).

arm is an "advantage." *See Allied*, 592 F.3d at 998-999; *supra* § II(G) (discussing both parties' experts' agreement that EEPROMs and RFIDs are commodity parts with many configurations). Intuitive has provided no evidence that its X/Xi wireless usage counter design change reduces manufacturing costs or prices to the consumers, or has improved the performance of the product that made it more attractive. *Id.* at 999; *supra* § II(B)(2), II(G).[19]

D. SIS's Lanham Act Should Proceed To Trial

The Lanham Act prohibits the use of a misleading description or misrepresentation of fact which misrepresents the nature of another person's goods, services or commercial activities. Challenged statements do not have to be literally false to violate the Lanham Act, although at the degree of certainty conveyed by Intuitive, they were. *E.g.*, JVH Dec. Ex.53 ("Engaging in such activities [to allow for use of EndoWrists beyond its labeled useful life] without first obtaining a new clearance to do so misbrands the product under 21 U.S.C. § 351."). Moreover, Intuitive's other statements under its "Impact to Regulatory Clearances" section of its threat letter, though peppered with "may" and "might", are also a basis for liability. [20] Intuitive's letters to SIS actual and potential hospital customers clearly conveyed the (false) impression that third party repair services are necessarily in violation of FDA regulations, and those letters caused hospitals to forego repair services that were otherwise in extremely high demand. Dkt. 127 at pp. 2-7; *supra* at § II(C), II(F).

IV. CONCLUSION

SIS's motion for summary judgment should be granted and Intuitive's motion denied.

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[19] Not only are Intuitive's claims that wireless connections have "improved consistency and reliability" incorrect (*supra* §§ II(A)(2), II(G)), but Intuitive does not present any evidence that such so-called "benefits" were regarded as improvements by its hospital customers, or even by Intuitive itself. Nor has Intuitive attempted to show that it promoted its wireless design to hospital customers as an improvement over the S/Si EndoWrist wired usage counter, or that it believed hospitals or surgeons would value a wireless usage counter.

[20] Even assuming Intuitive's statements are not literally false, a factual dispute exists regarding Intuitive's intent to mislead hospitals. Proof of intent to mislead gives rise to a presumption of actual consumer deception. *See William H. Morris Co. v. Grp.W, Inc.*, 66 F.3d 255, 258-259 (9th Cir.), supplemented, 67 F.3d 310 (9th Cir. 1995).

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